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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/092,954 03/06/2002 David D. Konieczynski 022719-0023 7357 21125 7590 12/02/2004 **EXAMINER** NUTTER MCCLENNEN & FISH LLP MAIORINO, ROZ WORLD TRADE CENTER WEST **ART UNIT** PAPER NUMBER 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 3763

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

			W
Office Action Summary	Application No.	Applicant(s)	
	10/092,954	KONIECZYNSKI ET AL.	
	Examiner	Art Unit	
	Roz Maiorino	3763	
The MAILING DATE of this communication	n appears on the cover sheet wi	th the correspondence address	
Period for Reply	EDIVIO OET TO EVDIDE AM	ONTHO FROM	
A SHORTENED STATUTORY PERIOD FOR R THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 Cl after SIX (6) MONTHS from the mailing date of this communication - If the period for reply specified above is less than thirty (30) days, - If NO period for reply is specified above, the maximum statutory properties to reply within the set or extended period for reply will, by any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	ON. FR 1.136(a). In no event, however, may a ron. a reply within the statutory minimum of thirt eriod will apply and will expire SIX (6) MON statute, cause the application to become AB	eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communicatic ANDONED (35 U.S.C. § 133).	on.
Status			
1) Responsive to communication(s) filed on	30 August 2004.		
,— .	This action is non-final.		
3) Since this application is in condition for all	owance except for formal matt	ers, prosecution as to the merits i	is
closed in accordance with the practice un	der <i>Ex parte</i> Q <i>uayle</i> , 1935 C.D	. 11, 453 O.G. 213.	
Disposition of Claims			
4)⊠ Claim(s) <u>1-40</u> is/are pending in the application	ation.		
4a) Of the above claim(s) 2, 4-6, 9, 12-13,		thdrawn from consideration.	
5) Claim(s) is/are allowed.		/	
6) Claim(s) <u>1,3,7,8,10,11,14-17,19,20,22,25</u>	and 28-40 is/are rejected.	(
7) Claim(s) is/are objected to.		•	
8) Claim(s) are subject to restriction a	and/or election requirement.		
Application Papers			
9) The specification is objected to by the Exa	miner.		
10) The drawing(s) filed on is/are: a)] accepted or b)☐ objected to	by the Examiner.	
Applicant may not request that any objection to			
Replacement drawing sheet(s) including the call 11) The oath or declaration is objected to by the			(d).
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for fo a) All b) Some * c) None of:	reign priority under 35 U.S.C. §	119(a)-(d) or (f).	
1. ☐ Certified copies of the priority docu	ments have been received.		
2. Certified copies of the priority docu		pplication No	
3. Copies of the certified copies of the			
application from the International B			
* See the attached detailed Office action for	a list of the certified copies not	received.	
.			
Attachment(s)			
1) Notice of References Cited (PTO-892)		Summary (PTO-413)	
2) Notice of Draftsperson's Patent Drawing Review (PTO-94	8) Paper No(s)/Mail Date nformal Patent Application (PTO-152)	
 Information Disclosure Statement(s) (PTO-1449 or PTO/S Paper No(s)/Mail Date 	6) Other:		
S. Patent and Trademark Office			

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1, 3, 10-11, 15, 17, 29-34, 36-40 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent NO. 6685452 to Christiansen et al.

Christiansen teaches an infusion pump including a fluid outlet; a fluid delivery pathway effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site; and a controlled release drug assembly, the drug assembly being

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configured for controllably releasing drug material, and communicating with the fluid delivery pathway such that the drug material is released into the fluid delivery pathway, wherein the pump assembly is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the fluid pathway discharges at the discharge portion to treat the target tissue site.

2. Claims 1, 3, 7-8, 10-11, 14-17, 19-20, 22, 25, 28-40 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent NO. 6517125 to Thompson.

Thompson teaches an infusion pump including a fluid outlet; a fluid delivery pathway effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site; and a controlled release drug assembly, the drug assembly being configured for controllably releasing drug material, and communicating with the fluid delivery pathway such that the drug material is released into the fluid delivery pathway, wherein the pump assembly is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the fluid pathway discharges at the discharge portion to treat the target tissue site. Drug assembly is a microchip; the system also comprises of biosensors.

Response to Arguments

3. Applicant's arguments with respect to claims 1, 3, 7-8, 10-11, 14-17, 19-20, 22, 25, 28-40 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 571-272-4960. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MICHOLAS D. LEGITATI Supervision patent from Coura